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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,907	11/02/2001	David Schaible	541.1029US2	6133

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EXAMINER	
HALPERN, MARK	
ART UNIT	**PAPER NUMBER**
1731	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,907	SCHAIBLE ET AL.	
	Examiner	Art Unit	
	Mark Halpern	1731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1) Acknowledgement is made of Amendment received 8/29/2005. Claims 1, 12, are amended, and claims 5, 25, are cancelled .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2) Claims 1, 4, 7-11, 27, are rejected under 35 U.S.C. 102(e) as being anticipated by Jollez et al. (2002/0084044).

Claim 1: Jollez discloses a process for making high grade, pharmaceutical grade microcrystalline cellulose. The process includes the following steps: (a) preparation of a pulp by repulping, (b) pressing of the pulp obtained in (a), (c) decompaction of the pulp obtained in (b), (d) feeding of the pulp obtained in (c) into a pre-heated reactor, (e) cooking of the pulp at a temperature, a time and a pressure allowing to obtain a pulp having a desired degree of polymerization, (f) cooling and partial controlled depressurization of the reactor by purging the reactor, followed by a water injection into the jacket and directly into the reactor, (This depressurization prevents a disorganized destruction of he cells and allows to obtain a higher yield of microcrystalline cellulose.) (g) filtering the pulp obtained in (f). After filtration the pulp is reacted with caustic soda

and washed in a water (pg. 9, lines 24-27). The pH of the solution being greater than 5.5 (pg. 12, lines 15-20). The cooked pulp is hydrolyzed cellulose. The process takes place without the use of mineral acids or sulphur dioxide, and in the absence of a violent non-selective depressurization. The process allows the application of a controlled depressurization in step (f), which in turn allows to keep the natural texture of the fibers and obtain a cellulose having a low degree of polymerization (pg. 4, line 5 to pg. 5, line 2). Deaggregating of the hydrolyzed cellulose takes place in "blender" type device, which allows the separation of microcrystalline cellulose particles (pg. 10, lines 19-23). Drying the hydrolyzed cellulose is performed in a spray dryer (pg. 10, lines 25-27).

Claim 4: drying occurs in a spray dryer (pg. 10, lines 25-27).

Claim 7: repulping is performed at a consistency of 2-3 % (pg. 7, lines 30-33).

Claim 8: antioxidants are added during the cooking step (pg. 7, lines 15-24).

Claim 9: cooking temperature is disclosed between 200 and 235 °C (pg. 8, lines 23-24).

Claim 10: cooking time is disclosed between 4 and 25 minutes (pg. 8, lines 30-31).

Claim 11: bleaching is performed using peroxide, magnesium sulphate and sodium hydroxide, or a mixture thereof. Bleaching occurs at a temperature ranging between 60 and 120 °C, and at an air pressure of 120 psi (pg. 9, line 21 to pg. 10, line 13).

Claim 27: the desired degree of polymerization is a stable degree of polymerization (pg. 8, line 30 to pg. 9, line 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3) Claims 2-3, 6, 12-24, 26, 28, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jollez.

Claims 2-3, 6: Jollez is applied as above for claim 1, Jollez is silent on the step of deaggregating comprises applying a shear force. Jollez discloses that the hydrolyzed cellulose is placed in "blender" type device, where water is added to homogenize the pulp , and where separation of microcrystalline cellulose particles takes place to give non colloidal microcrystalline cellulose (pg. 10, lines 19-23). It would have been obvious, to one skilled in the art at the time the invention was made, the blender action includes the applying of a shear force, as in a colloidal mill.

Claim 26: after filtration the pulp is reacted with caustic soda and washed in a water (pg. 9, lines 24-27). The pH of the solution being greater than 5.5, up to 10.5 (pg. 12, lines 15-20). It would have been obvious to one skilled in the art at the time the invention was made that the neutralization would result in a pH of a range claimed (pg. 12, lines 10-17).

Claim 12: Jollez discloses a process for making high grade, pharmaceutical grade microcrystalline cellulose. The process includes the following steps: (a) preparation of a pulp by repulping, (b) pressing of the pulp obtained in (a), (c)

decompaction of the pulp obtained in (b), (d) feeding of the pulp obtained in (c) into a pre-heated reactor, (e) cooking of the pulp at a temperature, a time and a pressure allowing to obtain a pulp having a desired degree of polymerization, (f) cooling and partial controlled depressurization of the reactor by purging the reactor, followed by a water injection into the jacket and directly into the reactor, (This depressurization prevents a disorganized destruction of he cells and allows to obtain a higher yield of microcrystalline cellulose.) (g) filtering the pulp obtained in (f). After filtration the pulp is reacted with caustic soda and washed in a water (pg. 9, lines 24-27). The pH of the solution being greater than 5.5 (pg. 12, lines 15-20). The cooked pulp is hydrolyzed cellulose. The process takes place without the use of mineral acids or sulphur dioxide, and in the absence of a violent non-selective depressurization. The process allows the application of a controlled depressurization in step (f), which in turn allows to keep the natural texture of the fibers and obtain a cellulose having a low degree of polymerization (pg. 4, line 5 to pg. 5, line 2). Deaggregating of the hydrolyzed cellulose takes place in "blender" type device, which allows the separation of microcrystalline cellulose particles (pg. 10, lines 19-23). Drying the hydrolyzed cellulose is performed in a spray dryer (pg. 10, lines 25-27). Jollez does not disclose that the hydrolyzed cellulose is fed into a colloidal mill. Jollez discloses that the hydrolyzed cellulose is placed in "blender" type device, where water is added to homogenize the pulp, and where separation of microcrystalline cellulose particles takes place to give non colloidal microcrystalline cellulose (pg. 10, lines 19-23). It would have been obvious, to one skilled in the art at

the time the invention was made, that the "blender" type device of Jollez is equivalent to a colloidal mill, since it performs the same function.

Claim 13: repulping is performed at a consistency of 2-3 % (pg. 7, lines 30-33).

Claim 14: antioxidants are added during the cooking step (pg. 7, lines 15-24).

Claim 15: cooking temperature is disclosed between 200 and 235 °C (pg. 8, lines 23-24).

Claim 16: cooking time is disclosed between 4 and 25 minutes (pg. 8, lines 30-31).

Claims 17-23: bleaching is performed using peroxide, magnesium sulphate and sodium hydroxide, or a mixture thereof. Bleaching occurs at a temperature ranging between 60 and 120 °C, and at an air pressure of 120 psi (pg. 9, line 21 to pg. 10, line 13).

Claim 28: the desired degree of polymerization is a stable degree of polymerization (pg. 8, line 30 to pg. 9, line 2).

Response to Amendment

4) Applicant's arguments filed 8/29/2005, have been fully considered but they are not persuasive.

Applicant alleges that the cited prior art, Jollez, does not disclose that the step of cooking the pulp is progressing until a desired degree of polymerization is obtained.

Jollez discloses that the cooking is performed until a stable degree of polymerization indicative of reaching the cellulose having the desired for MCC (pg. 8, line 30 to pg. 9, line 2).

Applicant alleges that the added step (j) of the process is not disclosed.

After filtration the pulp is reacted with caustic soda and washed in a water (pg. 9, lines 24-27). The pH of the solution being greater than 5.5 (pg. 12, lines 15-20).

Conclusion

5) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halpern whose telephone number is 571-272-1190. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Halpern

Mark Halpern
Primary Examiner
Art unit 1731